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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/691,959	10/24/2003	Ratan K. Chaudhuri	EMI-55	6979

23599 7590 07/10/2007
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EXAMINER	
LEITH, PATRICIA A	
ART UNIT	PAPER NUMBER
1655	

MAIL DATE	DELIVERY MODE
07/10/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/691,959	CHAUDHURI, RATAN K.	
	Examiner	Art Unit	
	Patricia Leith	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *2/28/07*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,9,10,12,13,17-24 and 31-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,9,10,12,13,17-24 and 31-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1, 9-10, 12-13, 17-24 and 31-33 are pending in the application and were examined on their merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 9-10, 12-13, 17-24 and 30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The newly recited ranges as present in claim 1 are deemed to be New Matter. It cannot be deduced where Applicant contemplated the ranges of 10-45% of Emblicanin A, above 0 to about 30% of Emblicanin B, about 3-40% of Pendunculagin or above 0 to about 22% of Punigloconin. While the Instant spec teaches that the disclosed ranges; i.e., 20-30% of Emblicanin a, 10-20% of Emblicanin B, 3-40% of Pendunculagin and 3-

12% of Punigloconin can deviate plus or minus 10%, it is not clear exactly what Applicant intends to mean by this statement. Mathematically speaking, it may mean that the lower amounts as disclosed may deviate plus or minus 10% from the lowest or highest value. Therefore, this could mean, for example, in the case of Emblicanin A, that the lower amount of Emblicanin A would be 10% of 10% - 10%, and the higher amount would be 10% of 40% + 40%. The Examiner cannot be absolutely sure however, because Applicant has not clearly stated what they mean by a 10% deviation. Therefore, it cannot be clearly determined that Applicant contemplated the ranges as Instantly claimed.

Because claims 9-10, 12-13, 17-24 and 30 depend either directly or indirectly upon claim 1, these claims necessarily possess all of the limitations of claim 1 and are therefore properly rejected under this statute for containing New Matter.

Upon further searching of the Invention, it is deemed that the following rejection is in order.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 9-10, 12-13, 17-18, 22-24 and 28-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chaudhuri, R (2002).

Chaudhuri, R. (2002) disclosed the anti-oxidative potential of *Emblica officinalis* extract, indicating that the standardized extract, containing 50% of the identified active ingredients of Emblicanin A, Emblicanin B, Pendunculagin and punigluconin were comparable to the antioxidant activities of well known anti-oxidants such as EDTA, pine antioxidant, Vitamin C, grape antioxidants and gallic acid (see entire reference, especially the Table on page. 377). This data is the same data as present in the Instant specification. Chaudhuri, R. further state that the benefits of the extract:

-A safe and effective natural antioxidant

Well –defined material

Pro-oxidation-free antioxidant

Dual functionality: chelation and antioxidant, two functions are separated

-Cascading effect provides long-lasting activity

-Statistically significant reduction in UV-induced pigmentation...

-Protection of skin fibroblast cells against oxidative stress (in vitro)

-excellent safety profile-edible fruit (see pp. 374-375).

Chaudhuri clearly describes *Emblica officinalis* as an "important Ayurvedic" herb found in India and further teaches that the herb "has been used for thousands of years for a variety of human ailments" (p. 374). Chaudhuri touts the *E. officinalis* standardized extract as an efficient antioxidating compound for prevention of skin photodamage (see p. 375). Oral toxicity testing in mice as well as clinical phototoxicity measurements verified the safety of the *E. officinalis* extract (see pp. 378-379).

Chaudhuri did not specifically teach oral administration of the *E.officinalis* extract, wherein the extract was taken at specific times prior to sun exposure, the particular ratios of Emblicanin A, Emblicanin B, Pendunculagin and punigluconin and flavonoids as Instantly claimed or wherein the extract was administered as a dose of 1-500 mg/day or about 2 – 200 mg/day.

It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F2d 454,456,105 USPQ 233; 235 (CCPA 1955). see MPEP § 2144.05 part II A. It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to determine all operable and optimal concentrations of Emblicanin A, Emblicanin B, Pendunculagin and punigluconin and dosage amounts because these phytochemicals were determined by Chaudhuri to be art-recognized result-effective variables which would have been *routinely optimized* in the pharmaceutical art. Further, it is clear that Chaudhuri already disclosed the anti-oxidant activity of the standardized extract of *E. officinalis* as compared to known antioxidants such as Vitamin C. One of ordinary skill in the art would have been motivated to adjust the amounts of Emblicanin A, Emblicanin B, Pendunculagin and punigluconin in the extract in order to achieve the same results as disclosed by Chaudhuri. It is further deemed that because flavonoids such as rutin were not taught as being an active ingredient for the anti-aging effects of the extract, one of ordinary skill in the art would have had a reasonable expectation that eliminating the flavonoids all together or only providing trace amounts of flavonoids such as rutin, and providing an extract which contained essentially only Emblicanin A, Emblicanin B, Pendunculagin and punigluconin would have worked effectively as an antioxidant for anti-aging of the skin.

Although the prior art does not specifically teach the extract for oral consumption for the treatment of skin photodamage, it is deemed that the ordinary artisan, drawing from the clearly disclosed anti-oxidant nature of the *E. officinalis* extract as well as the knowledge that these extracts have been used for centuries as oral medicaments particularly in the realm of aryuvedic medicine, that the antioxidant activity of the extract containing active ingredients of Emblicanin A, Emblicanin B, Pendunculagin and punigluconin would have provided for photodamage protection when taken orally. Chaudhuri already disclosed the antioxidant nature of this extract of *E. officinalis* and deemed that a standardized extract of *E. officinalis*, having protective effects from sun-induced photo damage of the skin was suitable for use in anti-aging products. Therefore, one of ordinary skill in the art would have been motivated to use the extract orally for protection from sun photo-damage at any time prior or during exposure to the sun. The differences between Applicant's claimed method and that suggested by the prior art appear minor in nature. Applicant has not performed any testing which would indicate that the particular amounts of active ingredients as claimed provide for any unexpected results over those results which were already disclosed by Chaudhuri. Nor has Applicant provided any indication that taking the medication orally would provide for any unexpected results.

Thus, it is deemed that the ordinary artisan would have had a reasonable expectation that topical application and/or oral administration of an *E. officinalis* would have provided for anti-aging effects.

Claims 1, 9-10, 12-13, 17-24, 31-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chaudhuri, R (2002) in view of Ghosal (US 2004/0166184 A1).

The teachings of Chaudhuri, R. were discussed *supra*. Chaudhuri did not specifically teach wherein the extract was combined with a foodstuff containing proteins, flour, a leavening agent, sweetener, water, flavoring agent or a colorant as required by claims 19-21 nor did Chaudhuri specifically teach wherein the extract was present at 'at least 0.1% of the composition.

Medicinally active agents are routinely added to foodstuffs in order to compound the active ingredients into edible forms for ease of administration of the active agents. Ghosal (US 2004/0166184 A1) disclosed a medicinally active extract of *Withania somnifera* administered in a foodstuff comprising proteins, flour, leavening agent, sweeteners, water, flavoring such as cherry and colorants such as pink and blue:

> 8. A nutritional supplement composition of claim 6 for producing a baked, edible, high protein product comprising (a) at least 0.25% Withania somnifera extract composition, (b) a mixture of high protein components, (c) flour, (d) leavening agent, (e) sweetener, and (f) water.
>
> 9. A nutritional composition according to claim 6, further including a flavor component for imparting a characteristic taste to said nutritional composition selected from the group consisting of water soluble natural or artificial extracts that include apple, banana, cherry, cinnamon, cranberry, grape, honeydew, honey, kiwi, lemon, lime, orange, peach, peppermint, pineapple, raspberry, tangerine, watermelon, wild cherry and equivalents thereof; being

in the overall range of 0.10% to 2.0% by weight of said dry composition.

10. A nutritional composition according to claim 6, further including a colorant component for imparting a characteristic color to said nutritional composition selected from the group consisting of water soluble natural or artificial dyes of blue, green, orange, red, violet, and yellow; iron oxide dyes, ultramarine pigments of blue, pink, red, and violet; and equivalents thereof; being in the overall range of 0.10% to 2.0% by weight of said dry composition (see claims 8-10).

It is seen that Ghosal disclosed the same amounts of flavoring and colorants as Instantly claimed.

One of ordinary skill in the art would have been motivated to optimize the amounts of active ingredients in the *E. officinalis* as Instantly claimed and to add this extract into a foodstuff as taught by Ghosal in order to ease the administration of the active components. It was well known in the art that medicinally active components were added to foodstuffs in order to provide the agents in a nutritionally fortified confectionary which suited individual tastes. Again, the adjustment of dosages of known, active ingredients is considered routine optimization in the art of pharmacology. One of ordinary skill in the art would have been motivated to adjust the amount of extract provided in the foodstuff in order to manufacture foodstuffs with varying medicinal potencies.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed

invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Leith whose telephone number is (571) 272-0968. The examiner can normally be reached on Monday - Friday 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Patricia Leith
Primary Examiner
Art Unit 1655

May 24, 2007